EXHIBIT A, Nicolette Sigrid Horbach, M.D.

Wooden, Brenda	2:12-cv-02951
Smallwood, Katherine	2:12-cv-03124

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Nicolette Sigrid Horbach, M.D.)

Pending before the court is the Motion to Exclude or Limit the Opinions and Testimony of Dr. Nicolette Sigrid Horbach [ECF No. 2044] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2044-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Nicolette Sigrid Horbach is board-certified in urogynecology. Over the course of her career, she has performed thousands of pelvic-floor repair surgeries.

a. General Methodology

The plaintiffs broadly challenge all of the opinions contained in Dr. Horbach's expert report because it contains few, if any, citations, despite referring to various unnamed studies and presenting specific statistics from those studies. Although it is clear that Dr. Horbach was relying on scientific literature based on the substance of her opinions and her extensive reliance list, the lack of citations makes it difficult to assess the reliability of her methodology. I am without sufficient information to draw the fine line between reliable and unreliable expert testimony, so I **RESERVE** ruling until the reliability and foundation of specific opinions may be evaluated firsthand at trial.

b. Alternatives

To start, the plaintiffs claim Dr. Horbach is not qualified to offer expert testimony on whether there are clinical differences between mechanical-cut and laser-cut mesh products. According to the plaintiffs, Dr. Horbach is not qualified because she does not know the difference between these types of mesh. This proposition is based on a gross mischaracterization and selective citation of Dr. Horbach's testimony, so I reject this argument. And I find that a urogynecologist who has extensive experience working with mechanical-cut and laser-cut mesh products—like Dr. Horbach—is qualified to offer expert testimony of this sort. The plaintiffs' Motion is **DENIED** on this point.

The plaintiffs also challenge the reliability of Dr. Horbach's expert testimony

about mechanical-cut and laser-cut mesh. Faced with this challenge, Ethicon argues that Dr. Horbach's clinical experience provides a reliable foundation for this expert testimony. Experience is especially essential, Ethicon emphasizes, because there is little literature comparing mechanical-cut and laser-cut mesh products.

In the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony. *See Kumho*, 526 U.S. at 156. But the reliability inquiry must probe into the relationship between the experience and the expert testimony:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, the court does not have enough information to judge the reliability or relevance of Dr. Horbach's particular experience.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on whether mechanical-cut mesh is safer than laser-cut mesh based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

c. Properties

First, the plaintiffs object to Dr. Horbach's opinion that she has never observed degradation in any of the specimens she has removed from her patients with mesh. They argue that Dr. Horbach is unqualified and that her testimony is based on a

flawed methodology because she did not keep sufficient records of her data and the microscope she used to examine mesh specimens was not powerful enough to detect degradation.

Ethicon does not address the alleged flaws in Dr. Horbach's methodology. As the court will not raise counterarguments for Ethicon, Dr. Horbach's testimony on degradation is **EXCLUDED** and the plaintiffs' Motion is **GRANTED** on this matter. Because the testimony is excluded on reliability grounds, I find it unnecessary to address Dr. Horbach's qualifications.

Second, the plaintiffs claim Dr. Horbach is unqualified to testify about the material characteristics of polypropylene mesh because she admits that she is not a biomedical engineer, materials engineer, nor has she ever designed a mesh sling. I disagree. Dr. Horbach is a board-certified urogynecologist who has performed thousands of pelvic floor surgeries over the course of her thirty years in clinical practice, including those using Ethicon's products. This extensive clinical experience, combined with Dr. Horbach's analysis of the relevant literature, qualifies her to opine on mesh's reaction to and effect on the human body. Additionally, to the extent the plaintiffs also challenge the reliability of Dr. Horbach's mesh properties opinions, their argument hinges on her lack of experience and is derivative of their qualifications challenge. The plaintiffs' Motion is **DENIED** on this matter

d. Warnings

The plaintiffs claim Dr. Horbach is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the

relevant Instructions for Use ("IFU"). According to the plaintiffs, Dr. Horbach is not an expert in the development of warnings labels and thus is not qualified to offer expert testimony about warnings. While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Horbach does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Horbach's expert testimony about these matters is **EXCLUDED**.[2]

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k)

[2] In relation to the expert testimony about the adequacy of the IFU, Ethicon claims Dr. Horbach is qualified to offer expert testimony about how doctors interpret IFUs and what results from misinterpreting an IFU. To the extent this expert testimony does not run afoul of my ruling, I offer no opinion on their admissibility because the plaintiffs' motion focuses on whether Dr. Horbach is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU.

clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's

quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope

of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose

of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude or Limit the Opinions and Testimony of Dr. Nicolette Sigrid

Horbach [ECF No. 2044].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 1, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

EXHIBIT A – HORBACH DAUBERT MOTION

THIS DOCUMENT RELATES TO PLAINTIFFS:

Kathleen Wolfe
Case No. 2:12-cv-00337

Cindy Smith
Case No. 2:12-cv-01149

Patricia Conti
Case No. 2:12-cv-00516

Marty Babcock
Case No. 2:12-cv-01052

Patti Ann Phelps
Case No. 2:12-cv-01171

Karyn Drake
Case No. 2:12-cv-00747

Exhibit C

Index of Relevant Pleadings related to Nicolette Sigrid Horbach, M.D.

Judge Goodwin instituted a series of Waves in MDL 2327 wherein he identified hundreds of cases per Wave subject to discovery and motion practice deadlines. As part of the Wave process, Judge Goodwin required parties to file one general causation *Daubert* motion per expert per Wave in the main MDL, rather than in each individual Wave case. Parties were required to identify the cases in each Wave to which a particular *Daubert* motion applied. The court has identified below, the relevant *Daubert* pleadings filed in each Wave (and in many cases ultimately adopted in subsequent Waves) for the court receiving this case on remand or transfer.

Wave 1	Date	WVSD ECF No.
Motion	4/21/16	2044
Memorandum	4/21/16	2045
Response	5/9/16	2183
Reply	5/16/16	2235
Mem Op & Ord	9/1/16	2714

Wave 2	Date	WVSD ECF No	Comment
Motion	7/21/16	2405	Adopts ECF No. 2044
Memorandum	7/21/16	2405	Adopts ECF No. 2045
Response	8/5/16	2491	Adopts ECF No. 2183
Reply	8/18/16	2602	Adopts ECF No. 2235
Mem Op & Ord			

Wave 3	Date	WVSD ECF No	Comment
Motion	9/16/16	2776	Adopts ECF No. 2044
Memorandum	9/16/16	2776	Adopts ECF No. 2045
Response	10/10/16	2907	Adopts in part ECF No. 2183
Reply	10/21/16	3046	Adopts ECF No. 2907